UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	[illegible]	FALK	R P-0800(0)-2

EXAMINER	
PESELEV, E	
ART UNIT	**PAPER NUMBER**
1211	2

12M2/0618

[illegible] HUGHES
[illegible]
175 [illegible] VALLEY
DRIVE [illegible] SUITE 200
[illegible] ONTARIO CANADA L3T 7P6

DATE MAILED: 06/18/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on ________ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ ________.

Part II SUMMARY OF ACTION

1. ☒ Claims 11, 119-121 and 184-186 are pending in the application.

   Of the above, claims ________ are withdrawn from consideration.

2. ☐ Claims ________ have been cancelled.

3. ☐ Claims ________ are allowed.

4. ☒ Claims 11, 119-121 and 184-186 are rejected.

5. ☐ Claims ________ are objected to.

6. ☐ Claims ________ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on ________. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ________. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed ________, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ________ ; filed on ________.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

The disclosure is objected to because of the following informalities: the specification is improper in that it is presented on both sides of the paper. However, the specification and the claims should be presented on separate pages. Appropriate correction is required.

Claims 11, 119-121 and 184-186 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology "and/or" (all accurrences) is in the alternative and renders the claimes indefinite because the scope of the invention cannot be determined. The terminology "tissue (including scar tissue)" (claims 11, 119 and 184) renders the claims indefinite because the scope of the invention cannot be determined i.e. it cannot be dertermined what other tissue besides scar tissue is encompassed bt the claims. Claims 119-121 and 184-186 are indefinite in that it cannot be determined if the same are composition or method claims. Applicants are required to rewrite said claims in accordance with the proper domestic terminology.

Claims 11, 119-121 and 184-186 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the specific embodiments. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The terms "homologues", "analogues", "derivatives", "complexes", "esters", "fragments" and "sub-units" lack enablement in that the same encompass a large number of compounds of diverse structural formulas and molecular weights and there is no guidince in the specification as to how to go about selecting specific compounds. Further, there is a good reason to expect that such diverse compounds as hyaluronic acid having a molecular weight of 8,000,000, hyaluronic acid having molecular weight of 3,000 and hyaluronic acid derivitized with protein will have the same ability to faciliate penetration of active components.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102

of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 11 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Della Valle et al (U.S. Patent No. 4,736,024).

Della Valle et al disclose the use of hyaluronic acid as a topical vehicle for various active ingredients (see, for example, column 1). The claimed method is anticipated therefrom. In addition, if there are any differences between the claimed method and the reference's method, the differences would appear to be minor in nature and the claimed method, which falls within the scope of the prior art's disclosure would have been prima facie obvious fron the said reference's disclosure to a person having ordinary skilll in the art at the time the instant invention was made.

Claims 1 , 119-121 and 184-186 are rejected under 35 U.S.C. § 103 as being unpatentable over Della Valle et al (U.S. Patent

No. 4,736,024) in combination with Lowry (U.S. Patent No. 4,900,550) and Karanewsky (U.S. Patent No. 4,711,884).

Della Valle et al disclose the use of hyalurovic acid for topical administration of drugs but do not disclose the use of hyaluronic acid with a diuretic. However, since Karanewsky disclose pharmaceutical application of a diuretic, such as furosemide (column 9, lines 55-68), a person having ordinary skill in the art at the time the instant invention was made would have been motivated to use the combination of hyaluronic acid and a diuretic in topical application because the said person would have expected the resulting composition to be useful as a diuretic. Further, Lowry disclose in columns 3-4, that a compsition containig hyaluronic acid is effective as a cell penetrant. Therefore, a person having ordinary skill in the art at the time the instant invention was made would have been further motivated to use hyaluronic acid as a topical vehicle for drugs in order to enhance their penetration.

Any inquiry concerning this communication should be directed to Elli Peselev at telephone number (703) 308-4616.

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200